

Official Title: Teen School-Night Sleep Extension: An Intervention Targeting the Circadian System

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Consent/assent form (last approved 1/8/19)

Investigator: Stephanie Crowley, Ph.D.

Contact Information: Biological Rhythms Research Laboratory
1645 W Jackson Blvd., Suite 425
Chicago, IL 60612
(312) 942-9991

Title of Study: Teen School-Night Sleep Extension: An Intervention Targeting the Circadian System (STUDY 2)

Sponsor: National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH)



Subject Information Sheet and Consent Form

The word “you” means both the person who takes part in the research, and the parent/legal guardian who gives permission to be in the research.

Introduction

You are invited to volunteer to take part in this research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully, as it may contain words you do not understand. You may wish to discuss it with your doctor, family, and/or friends. If there is anything that you do not understand or you would like more information, please ask questions and the study staff will try their best to answer them. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate.

You do not have to take part in this study. If you agree to take part, you will be asked to sign this form. Your signature means that you have read or had this form read to you and you have had all your questions answered by the study staff. Before you have anything done for this study, you must sign this form. A copy of this signed subject information sheet and consent form will be given to you. You will be free to withdraw from this study at any time you choose without giving a reason. This will not affect any future care you will receive. No promises can be made about the outcome of this as far as your current condition, either positive or negative. People who agree to be a part of a research study are called “subjects” instead of “patients”.

Why are you being invited to participate in this study?

You are being asked to take part in this study because you report good health and are between 14 and 17 years old. You also report a sleep pattern that we are interested in studying.

What is the purpose of this study?

The purpose of this study is to determine the effects of light on the timing of the body clock. This research will help in the development of methods to improve sleep, as well as daytime alertness and performance of people your age. In order to evaluate this

relationship very carefully and completely, you will be asked to keep careful records of your sleep and daily activities, and spend 2 or 3 weekends in our laboratory.

How many study subjects are expected to take part in the study?

About 60 study subjects will be enrolled in this study.

What will you be asked to do?

There are certain things you will be asked to do throughout the entire study which are described first. The rest of the study is broken up into multiple parts: "Home Sleep 1", "Lab Weekend 1", "Home Sleep 2", "Lab Weekend 2", "Home Sleep 3" and "Lab Weekend 3" which will all be described separately. All the procedures for this study are experimental.

Throughout the Duration of the Study

Throughout the duration of the study you will wear a wrist monitor, which looks like a wrist watch. It will record movements, and tell us when you are awake and when you are asleep.

You will also be required to communicate with the lab daily with your bed and wake times. Because the study requires frequent contact, it is important that you have a phone and internet access to use while in the study.

You will also wear a necklace with a small (1-inch by 1-inch) light sensor attached throughout the duration of the study; it looks like a medallion. You will need to make sure that the light sensor is always facing out and on the outside of your clothes and coat.

At the beginning of the study you will be required to complete a few short questionnaires. You will be required to keep daily records of your sleep times and other events (such as caffeine or medicine use) that occur that day while sleeping at home.

When you are not in school (such as after school to bedtime), you will be required to keep track of and report what you spend your time doing (homework, sports, hanging out with friends, and so forth).

You will be required to visit the lab 2 days per week (usually Monday's and Wednesdays after school) to deliver your daily questionnaires and to allow us to read your wrist activity data into our computer. This is another time to ask questions about the study if you have any. These visits will take about 30 minutes to 1 hour.

You will be asked to provide a urine sample at the beginning of the study for a drug/nicotine screen. You may also be randomly drug tested throughout the duration of the study. You will also be breathalyzed for alcohol at the start of each in-lab session.

You will be able to have caffeine on most days of the study before noon; however there are certain days that caffeine intake is prohibited. The days caffeine intake is prohibited are described below.

Home Sleep 1 (Days 1-14)

During these first 2 weeks of the study, you will sleep when you want to sleep, but you are not allowed to stay awake all night (“pull an all-nighter”). Caffeine intake is not allowed on days 12-14.

Lab Weekend 1 (Days 15-17)

On Friday afternoon after school, you will come to the lab for the first lab weekend. You will be in the lab until the session ends on Sunday afternoon. Food and beverages will be provided during this time, but some foods that could interfere with the study (such as, caffeine, bananas, and chocolate) will not be allowed.

On Friday and Saturday nights you will sleep in the lab in your own private bedroom. We will tell you when you need to go to bed and wake up in the morning. You will get about 9h to sleep each night.

You will complete performance tasks throughout the weekend. Some of these performance tasks maybe audio recorded. These audio recordings will be stored on our password protected server until the data are verified and data analysis is complete at which point the audio files will be deleted.

Saturday evening you will participate in a lazy boy session. You will participate with 1 or 2 other subjects. During a lazy boy session you will be asked to stay awake in dim red light in a lazy boy recliner chair for no more than 12 hours. You will provide a saliva sample (less than ½ teaspoon of saliva) every 30 minutes by rolling a small (less than ½ inch by a little more than 1 ½ inch) cylinder of dental cotton around in your mouth. You will provide no more than 30 saliva samples. Your saliva will be tested at a later time to determine how much melatonin is in your body. This will tell us what time it is in your brain. During the lazy boy session, you can watch T.V. and movies that have been approved by your parent or legal guardian. You can also play games or do other quiet activities with other subjects and a member of our research staff.

After the lazy boy session is over, you will sleep in our laboratory in your own private bedroom. We will schedule the time you have to go to bed. On Sunday, we will wake you up ~9 hours after you go to bed. You will leave the laboratory Sunday after you wake up.

Home Sleep 2 (Days 17-21)

After Lab Weekend 1, you will sleep at home for another week. You may be asked to follow a specific sleep schedule during these 5 nights (Sunday – Thursday) If you are given a sleep schedule you must follow the schedule within \pm 30 minutes. If you are not given a schedule for this week you will continue to sleep when you want. Additionally you may be given a time management plan to follow. The meeting during which this time management plan is explained to you may be audio recorded and will occur while you are in the lab over the weekend (Days 15-17). These audio recordings will be stored on our password protected Rush Network server. Whether or not you are required to follow a specific sleep schedule and/or are given a time management plan or not is determined randomly, by chance. Caffeine is prohibited on days 18-21 of the study.

Lab Weekend 2 (Days 22-24)

You may be asked to come in for a weekend lab session after Home Sleep 2. Half the study subjects in this study will be randomly selected (like the flip of a coin) to participate in this part of the study. If you are asked to come in for a lab session you will arrive on Friday afternoon and leave the laboratory the following Sunday. You will remain in the lab the entire weekend. Food and beverages will be provided this weekend, but some foods that could interfere with the study (such as caffeine, bananas, and chocolate) will not be allowed. During the wake periods, you can watch T.V. and movies that have been approved by your parent or legal guardian. You can also play games or do quiet activities. You will have time to complete your homework while in the laboratory. You will sleep in the lab on Friday and Saturday night in your own private bedroom.

On Friday and Saturday night you will go to bed earlier than you typically go to bed on weekends. On Saturday and Sunday morning we will wake you up earlier than you typically wake up on weekends. You will get ~8.5 hours in bed in the dark on Friday and Saturday night.

When you wake up on Saturday and Sunday mornings, you will be required to sit in front of a light box of fluorescent bulbs for 150 minutes each morning. During this time you can use our computer to watch movies/TV, work on homework etc. The lights will produce bright light that is brighter than most indoor light, but not as bright as being outside on a cloudy day. The light box is safer than sunlight because it does not contain ultraviolet (UV) light. There are no known harmful effects from light of this intensity, but rarely people experience headaches.

At the end of the bright light session on Sunday morning you will leave the laboratory.

If you are not asked to come into the lab this weekend you will continue to sleep at home when you want. Whether or not you are required to come into the laboratory this weekend or not is determined randomly, by chance.

Home Sleep 3 (Days 24-28)

On days 25-28 you will sleep at home for another week. You may or may not be asked to follow a specific sleep schedule during these 5 nights. If you are given a sleep schedule you must follow the schedule within ± 30 minutes. Additionally you may be asked to follow a time management plan this week. If you are not given a schedule or time management plan for this week you will continue to sleep when you want and spend your time as you wish. Whether or not you are required to follow a specific sleep schedule/time management plan or not is determined randomly, by chance. Caffeine is prohibited on Days 26-28.

Lab Weekend 3 (Days 29-31)

On Friday afternoon after school, you will come to the lab for another lab weekend. You will be in the lab until the session ends on Sunday afternoon. This lab weekend will be exactly like lab weekend 1.

How long will you be in the study?

Successful completion of this study will take no more than 31 days.

You may be removed from this study without your consent for any of the following reasons: failed drug/nicotine/alcohol screen, the study doctor decides that continued participation in the study will be harmful to you, you do not follow the study rules, you will need a treatment not allowed on the study, the study is canceled, or your sleep schedule during home sleep is very different from what you reported on your preliminary questionnaires.

What are the possible risks of the study?

There is no known risk to wearing an activity monitor or light sensor, or using cotton swabs to provide a small saliva sample. There is a chance that you may develop a headache if you are asked to sit in front of the light boxes. If you become pregnant during the study, it is unknown whether the study procedures would harm the baby. You will be told of any new information that may affect your willingness to participate in this research study.

Female

If you are a female, we need to keep track of when you get your menstrual period during the study. You must indicate whether or not you get your period on your daily records. We need to know this for research purposes only, in order to analyze the data properly. If you become pregnant, you must notify the study staff immediately. If you become pregnant, we will have to drop you from the study. If you become pregnant, we will not share this information with your parents.

Are there benefits to taking part in the study?

We cannot and do not guarantee or promise you any direct benefit from this study. In terms of the benefits to society, we hope to understand the effects of bright light on the body clock, which may help us more accurately study and treat sleep disorders in people your age.

What other options are there?

The only alternative to participating in this study is not to participate.

What about confidentiality of your information?

Records of participation in this research study will be maintained and kept confidential as required by law. We will assign you a special code name while you are in the study. The data we collect from this study will be labeled with your code name instead of your name or other personal identifiers to keep your identity confidential. In addition to our staff, the National Institute of Health (the people who fund this study) will be granted access to the data you provide, without violating your confidentiality, to the extent permitted by law and regulations. Your identity will not be revealed on any report, publication, or at scientific meetings.

We will do everything we can to keep others from learning about your participation in this study. To further help us protect your privacy; we have obtained a Certificate of Confidentiality from the United States Department of Health and Human Services (DHHS).

With this Certificate, we cannot be forced (for example by court order or subpoena) to disclose information that may identify you in any federal, state, local, civil, criminal, legislative, administrative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except to prevent serious harm to you or others, and as explained below.

A Certificate of Confidentiality does not prevent you, or a member of your family, from voluntarily releasing information about yourself, or your involvement in this study.

If an insurer or employer learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Disclosure will be necessary, however, upon request of DHHS for the purpose of audit or evaluation, and is limited only to DHHS employees involved in the review.

We will in all cases take the necessary action, including reporting to authorities, to prevent serious harm to yourself, children, or others. For example, in the case of child abuse or neglect.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews human research to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is entitled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

What are the costs of your participation in this study?

There is no cost to you or your parents/legal guardian to participate in this study.

Will you be compensated or paid?

You (the study subject) will be paid \$1,000 after successful completion of this study. Successful completion includes: 1) you wear the study equipment (wrist monitor and/or light sensor) correctly, fully completed daily sleep and event records, and leave daily telephone messages during the home sleep part of the study; 2) you come to the lab appointments so that we can look at your daily records, activity monitor data, and light sensor data; and 3) you come to our lab for all lab weekends assigned to you. Your check will be processed after all your forms are received and all of your equipment (wrist monitor and light sensor) is returned. Your check will arrive by mail within 4 weeks of completion of the study.

We will pay for parking in our attached garage when you come to our laboratory.

We will deduct \$5 from your final payment for each missed phone call, each missed morning or bedtime sleep log, and each missed day of activity tracking during the home sleep part of the study.

Unless you complete the entire study, we cannot use your data. Therefore, if you leave the study, you will be paid \$10 for each day completed. If we have to drop you from the study because you did not follow the rules (such as you take the activity monitor off your wrist, you are late for lab weekend, you fail a drug/nicotine/alcohol screen, you leave during the lab weekend, or you have incomplete daily records), then you will be paid \$10 per day completed. If we have to drop you for reasons that are not your fault (such as equipment failure), then you will be paid \$20 per day completed. If you are dropped from the study, you will not lose money for missed phone calls.

We must report your payment to the Internal Revenue Service. We will collect your social security number at the beginning of the study for reporting purposes.

Your participation in this research study may contribute to the development of commercial products from which the sponsor or others may derive economic benefit. You will have no rights to any products, patents, or discoveries arising from this research and you will receive no economic benefit.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. Your insurance company may not pay. No funds have been set aside for any losses such as lost wages, disability, or discomfort relating to injury or illness as a result of your participation in this study. You will be responsible for any costs resulting from participation in this research study if your insurance does not pay.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

What happens if you need emergency care?

If you need emergency care while you are participating in this study, it is important that you inform emergency personnel of your participation in this study.

Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact the staff at the Biological Rhythms Research Lab at (312) 942-9991 or the study director, Dr. Stephanie Crowley at (312) 563-4783. Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 312-942-5498.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study personnel. You do not waive any of your legal rights by signing this consent document. You will be given a copy of the signed and dated consent document for your records.

SIGNATURE BY THE SUBJECT AND THE SUBJECT’S LEGAL GUARDIAN:

MINOR ASSENT

Signature of Subject (child) Date of Signature

Print full name of Subject (child) Print Subject Code Name

PARENTAL CONSENT

Parent, Guardian or Legal Representative’s Signature Date of Signature

Print Parent, Guardian or Legal Representative’s full name Relationship to Subject

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:

I attest that all the elements of informed consent described in this document have been discussed fully in non-technical terms with the subject or the subject’s legally authorized representative. I further attest that all questions asked by the subject or the subject’s legal representative were answered to the best of my knowledge.

Signature of Individual Obtaining Consent Date of Signature

Check here if the Individual Obtaining Consent observed the signing of this consent document and can attest, to the best of their knowledge, the person signing the consent form is the subject or the subject’s legally authorized representative and the person signing the form has done so voluntarily. By checking this box, the Individual Obtaining Consent does not need to sign on the Witness signature line (below).

SIGNATURE BY WITNESS/TRANSLATOR:

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the subject or the subject’s legally authorized representative and the person signing the form has done so voluntarily.

Signature of Witness/Translator Date of Signature

Check here if a separate witness signature is not necessary.

SIGNATURE OF THE PRINCIPAL INVESTIGATOR:

I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator

Date of Signature

Check here if Principal Investigator obtained consent and a separate signature is not required.